

This listing of claims will replace all prior versions, and listings, of claims in the application:

**Listing of Claims**

1. (Currently Amended) A composition comprising a *Bacillus* species in a pharmaceutically acceptable carrier suitable for topical application to skin or a mucous membrane of a mammal, wherein the composition is in the form of an emulsion, cream, lotion, gel, oil, ointment, suspension, aerosol spray, powder, aerosol powder or semi-solid formulation.
2. (Original) The composition of Claim 1, wherein the *Bacillus* species is included in the composition in the form of spores.
3. (Original) The composition of Claim 1, wherein the *Bacillus* species is included in the composition in the form of a dried cell mass.
4. (Original) The composition of Claim 1, wherein said *Bacillus* species is selected from the group consisting of *Bacillus coagulans*, *Bacillus subtilis*, *Bacillus laterosporus* and *Bacillus laevolacticus*.
5. (Currently Amended) The composition of Claim 1 wherein said composition comprises ~~contains~~  $10^3$  to  $10^{12}$  viable bacteria ~~bacterium~~ or spores per gram of composition.
6. (Currently Amended) the composition of Claim 1 further comprising an effective amount of a fructo-~~oligosecharide~~ oligosaccharide (FOS).
7. (Original) The composition of Claim 6 wherein said FOS is present in an amount of from about 10 to 1000 milligrams per gram of composition.
8. (Original) The composition of Claim 6 wherein said FOS is present in an amount of from about 100 to 500 milligrams per gram of composition.
9. (Canceled).

10. (Original) A composition comprising an extracellular product of a *Bacillus coagulans* strain in a pharmaceutically acceptable carrier suitable for topical application to skin or a mucous membrane of a mammal.

11. (Original) the composition of Claim 10, wherein the extracellular product is a supernatant or filtrate of a culture of a *Bacillus coagulans* strain.

12. (Currently) The composition of Claim 10, wherein the composition ~~earlier~~ is an emulsion, cream, lotion, gel, oil, ointment, suspension, aerosol spray, powder, aerosol powder or semi-solid formulation.

13. (Original) the composition of Claim 10 which further comprises about 1-75% emu oil by weight.

14. (Original). A method of preventing bacterial, yeast, fungal or viral infection comprising: applying topically to skin or a mucous membrane of a mammal a probiotic composition comprising a *Bacillus species*; and allowing the *Bacillus species* to grow topically for sufficient time to inhibit growth of bacteria, yeast, fungus or virus.

15. (Original) The method of Claim 14, further comprising the steps of providing spores of the *Bacillus species* in the probiotic composition, and allowing the spores to germinate after the applying step.

16. (Original). The method of Claim 14 wherein said *Bacillus species* is selected from the group consisting of *Bacillus coagulans*, *Bacillus subtilis*, *Bacillus laterosporus* and *Bacillus laevolacticus*.

17. (Currently Amended) The method of Claim 14 wherein said composition comprises contains 103 to 10<sup>12</sup> viable ~~bacterium~~ bacteria or spores per gram of composition.

18. (Currently Amended) The method of claim 14 wherein said administering comprises applying from  $10^8$  to  $10^{10}$  viable ~~bacterium~~ bacteria or spores per day.

19. (Currently Amended) The method of claim 14 wherein said administering comprises applying from  $5 \times 10^8$  to  $10^9$  viable ~~bacterium~~ bacteria or spores per day.

20. (Currently amended). The method of Claim 14 further comprising an effective amount of a fructo-oligosaccharide oligosaccharide (FOS).

21. (Original) The method of Claim 20 wherein said FOS is present in an amount of from about 10 to 1000 milligrams per gram of composition.

22. (Original) The method of Claim 20 wherein said FOS is present in an amount of from about 100 to 500 milligrams per gram of composition.

23. (Original) The method of Claim 14, wherein the step of allowing the *Bacillus* species to grow inhibits growth of one or more microbes selected from the group consisting of *Staphylococcus* species, *Pseudomonas* species, *Escherichia coli*, *Proteus* species, *Klebsiella* species, *Candida* species and *Trichophyton* species.

24. (Original) The method of Claim 14, wherein the applying step comprises applying a probiotic composition in the form of a cream, lotion, gel, oil, ointment, suspension, aerosol spray, powder, aerosol powder or semi-solid formulation.

25. (Original) A method of inhibiting growth of bacteria, yeast, fungus, virus or a combination thereof, comprising: applying topically to skin or a mucous membrane a composition comprising an extracellular product of a *Bacillus coagulans* strain; and allowing the composition to be present for sufficient time to inhibit growth of bacteria, yeast, fungus, virus or any combination thereof

26. (Original) The method of Claim 25, wherein the applying step comprises applying the composition in the form of a cream, lotion, gel, oil, ointment, suspension, aerosol spray, powder,

aerosol powder or semi-solid formulation.

27. (Original) the method of claim 25 wherein said composition further comprises about 1-75 % emu oil by weight.

28. (Original) An article of manufacture comprising a flexible article and an effective amount of a *Bacillus* species applied to said flexible article, wherein said flexible article is intended to be worn by or attached to skin or a mucous membrane of a mammal to allow probiotic activity of the isolated *Bacillus* species to occur adjacent to or on the skin or mucous membrane.

29. (Original) The article of manufacture of Claim 28 wherein said *Bacillus* species is selected from the group consisting of *Bacillus coagulans*, *Bacillus subtilis*, *Bacillus laterosporus* and *Bacillus laevolacticus*.

30. (Currently Amended) The article of manufacture of Claim 28 wherein said effective amount is about  $10^3$  to  $10^{10}$  viable ~~bacterium~~ bacteria or spores per article.

31. (Currently Amended) the article of manufacture of Claim 28 further comprising an effective amount of a fructo-~~oligoseecharide~~ oligosaccharide (FOS).

32. (Original) The article of manufacture of Claim 31 wherein said FOS is present in an amount of from about 10 to 1000 milligrams per article.

33. (Currently Amended) The article of manufacture of Claim 28 wherein said article is selected from the group consisting of a bandage, a tampon, a feminine hygiene napkin, ~~or~~ and an article of clothing.

34. (Original) A method of inhibiting growth of bacteria, yeast, fungus, virus or any combination thereof, comprising: applying a composition comprising a *Bacillus* species to a solid surface; contacting the solid surface with the applied *Bacillus* species thereon to skin or a mucous membrane of a mammal; and allowing the solid surface to contact the skin or mucous membrane for sufficient time to allow initiation of probiotic activity of the isolated *Bacillus* species to inhibit growth of bacteria, yeast, fungus, virus or a combination thereof adjacent to or on the skin or mucous membrane.

35. (Currently Amended) The method of Claim 34, wherein the solid surface comprises a flexible article selected from the group consisting of a diaper, pliable material for wiping skin or a mucous membrane, dermal patch, adhesive tape, absorbent pad, tampon ~~or~~ and article of clothing.

36. (Original) the method of Claim 34, wherein the applying step comprises impregnating the composition into a fibrous or nonfibrous solid matrix.

37. (Original) the method of Claim 34, wherein the *Bacillus* species is included in the composition in the form of spores.

38. (Original) The method of Claim 34, wherein the *Bacillus* species is included in the composition in the form of a dried cell mass.

39. (Original). The method of Claim 34 wherein said *Bacillus* species is selected from the group consisting of *Bacillus coagulans*, *Bacillus subtilis*, *Bacillus laterosporus* and *Bacillus laevolacticus*.

40. (Currently Amended) The method of Claim 34 wherein said composition comprises contains  $10^3$  to  $10^{12}$  viable ~~bacterium~~ bacteria or spores per gram of composition.

41. (Currently Amended) The method of Claim 34 further comprising an effective amount of a fructo-~~oligosaccharide~~ oligosaccharide (FOS).
42. (Original) The method of Claim 41 wherein said FOS is present in an amount of from about 10 to 1000 milligrams per gram of composition.
43. (Original) The method of Claim 41 wherein said FOS is present in an amount of from about 100 to 500 milligrams per gram of composition.
44. (Original) A therapeutic system for inhibiting growth of bacteria, yeast, fungus, virus, or a combination thereof comprising a container comprising a label and a composition comprising *Bacillus* according to Claim 1 wherein said label comprises instructions for use of the composition for inhibiting said growth.
45. (New) A composition comprising *Bacillus coagulans* bacteria and a carrier, wherein the composition is in the form of a douche, bath salt, soap, bath powder, bath oil or suppository.
46. (New) The composition of claim 45, wherein the *Bacillus coagulans* are in the form of spores.
47. (New) The composition of claim 45, wherein the *Bacillus coagulans* are in the form of vegetative cells.
48. (New) The composition of claim 45, wherein said composition contains  $10^3$  to  $10^{12}$  viable bacteria or spores per gram of composition.
49. (New) A method of preventing or treating a vaginal infection, comprising: identifying a subject suffering from or at risk of developing a vaginal infection; and applying topically to the skin or a mucous membrane of said subject a composition comprising *Bacillus coagulans* bacteria.

50. (New) The method of claim 49, wherein said infection is caused by a pathogen, wherein said pathogen is selected from the group consisting of bacteria, yeast, fungus, virus, and a combination thereof.

51. (New) The method of claim 50, wherein said yeast pathogen is selected from the group consisting of *Candida albicans*, *Candida tropicalis*, and a combination thereof.

52. (New) The method of claim 50, wherein said bacterial pathogen is selected from the group consisting of *Staphylococcus*, *Streptococcus*, *Pseudomonas aeruginosa*, enterohemorrhagic *Escherichia coli*, *Clostridium perfringens*, *Clostridium difficile*, *Gardnerella vaginalis*, *Propionibacterium acnes*, *Aeromonas hydrophilia*, *Aspergillus*, *Proteus* and *Klebsiella*.

53. (New) The method of claim 50, wherein said fungal pathogen is selected from the group consisting of *Trichophyton mentagrophytes*, *T. interdigitale*, *T. rubrum*, and *T. yaoundei*.

54. (New) The method of claim 50, wherein said viral pathogen is selected from the group consisting of Herpes simplex virus I and II.

55. (New) The method of claim 49, wherein said composition is in a form selected from the group consisting of a douche, bath salt, soap, powdered bubble bath, bath powder, bath oil, cream, liquid, powder, non-soap emollient cleanser, suppository, soft towelette, and aerosol microparticulate.

56. (New) The method of claim 49, wherein the *Bacillus coagulans* bacteria are in the form of spores.

57. (New) The method of claim 49, wherein the *Bacillus coagulans* bacteria are in the form of vegetative cells.

58. (New) The method of claim 49, wherein said composition contains  $10^3$  to  $10^{12}$  viable bacteria or spores per gram of composition.

59. (New) The method of claim 55, wherein said bath oil further comprises mineral oil, laureth-4, quaternium-18 hectorite and phenylcarbinol.

60. (New) The method of claim 55, wherein said bath oil further comprises olive oil, grape seed oil, emu oil, sweet almond oil, geranium oil, grapefruit oil, mandarin oil or peppermint oil.

61. (New) The method of claim 55, wherein said bath oil further comprises a fragrance.

62. (New) The method of claim 55, wherein said non-soap emollient cleanser further comprises sodium octoxynol-2 ethane sulfonate, petrolatum, octoxynol-3, mineral oil, lanolin oil, cocamide MEA, or imidazolidinyl urea.

63. (New) The method of claim 55, wherein said soft towelette further comprises potassium sorbate and disodium EDTA.

64. (New) The method of claim 55, wherein said moist towelette further comprises DMDM hydantoin, isopropyl myristate, methylparaben, polysorbate 60, propylene glycol, propylparaben or sorbitan stearate.

65. (New) The method of claim 55, wherein said moist towelette is disposable.

66. (New) The method of claim 55, wherein said vaginal infection comprises bacterial vaginosis.

67. (New) The method of claim 55, wherein a symptom of said vaginal infection is selected from the group consisting of vaginal itch and discharge.



68. (New) The method of claim 49, wherein said composition is in the form of a vaginal suppository or insert comprising from about  $10^6$  to  $10^{12}$  viable *Bacillus coagulans* bacteria.

69. (New) The method of claim 68, wherein between one and about three suppositories or inserts are used per day for a consecutive period of time of about three to about seven days.